UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, ex rel. [UNDER SEAL], Plaintiffs, v. [UNDER SEAL], Defendants.	Case No. COMPLAINT **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)**

DOCUMENT TO BE KEPT UNDER SEAL

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA and the State of TENNESSEE, ex rel. GARY ODOM and ROSS LUMPKIN Plaintiffs, vs. SOUTHEAST EYE SPECIALISTS, PLLC., SOUTHEAST EYE SURGERY CENTER, LLC., and EYE SURGERY CENTER OF CHATTANOOGA, LLC. Defendants.	Case No. COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)** **JURY TRIAL DEMANDED**

COMPLAINT

Pursuant to the *qui tam* provisions of federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, (the "False Claims Act" or the "FCA"), *qui tam* Plaintiff-Relators Mr. Gary Odom and Dr. Ross Lumpkin (hereinafter "Relators"), on behalf of the United States of America and the State of Tennessee for this Complaint against SouthEast Eye Specialists, PLLC., Southeast Eye Surgery Center, LLC., and Eye Surgery Center of Chattanooga, LLC. ("Defendants"), allege as follows:

I. INTRODUCTION AND OVERVIEW

1. Through a scheme of paying for patient referrals, in the form of kickbacks and improper fee splitting related to eye surgery, Defendants have defrauded—and continue to defraud—Medicare and Medicaid of tens of millions of dollars.

2. SouthEast Eye Specialists, PLLC ("SEES"), one of the largest ophthalmology groups in Tennessee, limits its practice to eye surgery. SEES restricts its surgeons and staff optometrists from performing most routine eye care.

3. Most of SEES' surgical patients are referred by optometrists. Optometrists perform routine eyecare, including examinations and prescribing corrective lenses. When they

diagnose cataracts, glaucoma, and other eye conditions requiring surgery, optometrists often refer their patients to ophthalmologists like SEES.

4. Optometric referrals are the lifeline of SEES' practice. In order to strengthen this lifeline, SEES illegally induces optometrists to refer their patients for surgery.

5. The heart of this illegal inducement is a "co-management" arrangement. Co-management in this context is the ophthalmologists performing surgery and the referring optometrist providing the post-operative care and sharing in the fee. The surgeon receives 80% of the Medicare or Medicaid fee and the optometrist receives 20% of the Medicare or Medicaid fee.

6. The co-management model was designed exclusively for the benefit of the patient. It is appropriate and beneficial when it is arranged on a patient-by patient basis and is based on the needs of the patient.

7. But SEES does not use it for patient benefit at all, it uses it exclusively for its own financial benefit and for the financial benefit of its referring optometrists.

8. SEES promotes this routine co-management model as a revenue opportunity for referring optometrists, encouraging referrals in exchange for fees and a promise not to compete for routine eye care.

9. SEES has fraudulently transformed co-management from a patient care tool to its primary marketing tool.

10. SEES' own words explain how the co-management model benefits referring optometrists. Specifically, SEES has stated that its "real goal is to keep as much patient revenue in your practice as we can." They tell the optometrists, "our clients are you all." They say that the patients "should come in already expecting" co-management and to be seen post operatively by optometrists.

11. This marketing approach vividly illustrates that co-management is essentially a fait accompli. When used in this manner—as it is with SEES—it is a payment for referrals, or a kickback.

12. While SEES utilizes this illegal arrangement for many surgical procedures, the most common situation is surgery to correct cataracts.

13. A cataract is a clouding of the eye's natural lens, causing progressive vision loss. In cataract surgery, the natural human lens is removed and replaced with a clear artificial lens, also known as an intraocular lens or "IOL." Cataracts are typically detected by optometrists during routine eye care, who then refer patients to an ophthalmic surgeon that removes and replaces the clouded lens. Cataract surgery is one of the most commonly performed elective surgical procedures in the United States.

14. Following cataract surgery, a patient requires 90 days of post-operative care. In a co-managed patient relationship, the patient returns to their referring optometrist for their post-operative care, instead of receiving care from the ophthalmic surgeon who performed the surgery. In certain circumstances, Medicare and Medicaid allow billing for appropriate co-management: in a co-managed relationship, the referring optometrist receives 20% of the Medicare or Medicaid global surgical fee. The ophthalmic surgeons and referring optometrists receive additional fees, directly from a patient or private insurance, if the patient also elects to have a "premium" vision-correcting lens inserted.

15. Though the Anti-Kickback Statute has a safe harbor for specialist referrals, the safe harbor ***does not*** apply to global fee splitting arrangements such as cataract co-management. In fact, in declining to extend the safe harbor, HHS-OIG specifically cited concerns about this exact arrangement—*routine agreements* between referring optometrists and ophthalmic surgeons for cataract surgery.

16. Echoing these concerns, the American Academy of Ophthalmology—the largest professional association of the field—has noted in position papers that routine co-management is inappropriate. Instead, co-management should follow patient specific protocol, informed patient consent, and assessments of clinical appropriateness in every case.

17. Despite clear professional prohibitions on routine agreements and HHS-OIG warnings, SEES practices routine co-management to induce patient referrals from optometrists.

18. SEES promotes these practices by sponsoring free continuing medical education courses and dinners for optometrists who may potentially refer patients. In these courses and dinners, SEES routinizes the practice; it encourages optometrists to steer patients into expecting co-management prior to surgery, to avoid patient requests to the surgeon to remain with the surgeon for post-operative care. SEES also actively advertises their routine co-management of patients as a revenue generating opportunity for optometrists.

19. Through routine co-management, SEES guarantees that optometrists receive, in return for their referral of patients: 20% of the patient's Medicare or Medicaid-funded global surgery fee, approximately 10% of the patient-funded vision correction fee (if applicable) and return of the patient's future business to the optometrist without competition from SEES for routine eye care.

20. SEES receives the patients for surgery, which allows it to bill Medicare and Medicaid for 80% or more of the global surgery fees, as well as other lucrative fees such as the initial exam and ancillary testing fees.

21. Not only does SEES collect these substantial and improper professional fees from the Government, but its affiliated surgical centers, co-Defendants Southeast Eye Surgery Center and Eye Surgery Center of Chattanooga—whose officers are the same as SEES officers and/or co-founders—collect substantially greater fees by virtue of their ownership and/or control of these surgical centers where most of SEES' procedures are performed.

22. Each improperly induced surgical procedure performed at these surgical centers results in facility, anesthesia and other ancillary fees which likely exceed all professional fees combined.

23. This practice of routine co-management has contributed to SEES becoming one of the largest ophthalmological referral centers in Tennessee, if not the entire southeast United States.

24. Relators Gary Odom and Ross Lumpkin seek, through this action, to recover damages and civil penalties arising from the false or fraudulent records, statements and/or claims that Defendants knowingly made or caused to be made in connection with its fraudulent scheme.

II. PARTIES

25. Relator Mr. Gary Odom has served as Executive Director of the Tennessee Association of Optometric Physicians since 1981. He previously served as an Investigator for Tennessee's Division of Health Regulatory Boards, a Special Investigator for the State Attorney General's Office (Nashville), and as a Representative in the Tennessee House of Representatives.

26. Relator Dr. Ross Lumpkin, O.D., is an optometrist currently practicing in Nashville, Tennessee. He is a past president of the Tennessee Association of Optometric Physicians. He received his Doctor of Optometry from the Southern College of Optometry in 2010 and has remained in practice over the past seven years.

27. Relators became aware of the fraud as members of the optometric community. Mr. Odom and Dr. Lumpkin began noticing severe declines in optometrist attendance at state association continuing medical education seminars. Relators learned that SEES and other practices had begun promoting many more free seminars and dinners around 2010. Through reading these promotional materials, word-of-mouth at professional events, and discussions with other practitioners, Relators became aware that SEES and other practices nationwide used routine co-management to induce optometrist referrals. In 2016, Dr. Lumpkin attended a SEES continuing medical education seminar for the first time: there, he personally heard and recorded SEES representatives promoting co-management as a revenue opportunity for optometrists. Dr. Lumpkin attended two additional SEES seminars and heard and recorded similar SEES promotional pitches.

28. Defendant SouthEast Eye Specialists, PLLC is a medical practice group headquartered at 7268 Jarnigan Road, Suite 200, Chattanooga, TN 37421-3097. SEES maintains it is a referral center and ***only*** receives patients through referrals from either optometrists or medical doctors. SEES has operated since 1999 and has surgical centers in Chattanooga, Knoxville and Nashville, as well as 15 other satellite offices through Tennessee. The SEES surgical group currently includes 9 M.D.s (ophthalmic surgeons) and 9 O.D.s (optometrists), and performs ~12,000 cataract surgeries a year.

29. Defendants Southeast Eye Surgery Center, LLC and Eye Surgery Center of Chattanooga, LLC are licensed health care facilities, which operate SEES' ambulatory surgical treatment centers in Knoxville, TN and Chattanooga, TN, respectively. SEES performs many of the Medicare/Medicaid funded procedures described below at these surgery centers: these centers receive facility and other ancillary fees for SEES' surgeries.

30. Southeast Eye Surgery Center, LLC's registered agent is SEES Co-Founder Dr. John Bierly, at 7268 Jarnigan Road, Suite 200, Chattanooga, TN 37421-3097. Its sole officers are SEES Co-Founders and current officers Dr. John Bierly and Dr. Daryl Mann.

31. The Eye Surgery Center of Chattanooga, LLC's registered agent is also SEES Co-Founder Dr. John Bierly, at 7268 Jarnigan Road, Suite 200, Chattanooga, TN 37421-3097. Its sole officers are current SEES officers, Dr. John Bierly and Dr. Daryl McDaniel.

32. Flexpoint Ford, LLC ("Flexpoint Ford"), a private equity firm focused on the healthcare and financial services sectors, announced on February 27, 2017 that it formed a partnership with SouthEast Eye Specialists and its affiliates and now has a "stake" in SEES' practice. As described by SEES Co-Founder Dr. Daryl Mann: "We chose to partner with the Flexpoint Ford team based upon their deep experience in healthcare services and understanding of the importance of our practice's co-management model." Iris Dorbian, Flexpoint Ford Backs SEES and Center for Facial Rejuvenation. PE Hub Network (Feb. 27, 2017), available at https://www.pehub.com/2017/02/3438214/.

III. JURISDICTION AND VENUE

33. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

34. Although the issue is no longer jurisdictional, the public disclosure provisions of the federal False Claims Act do not bar this suit. To the extent there has been a public disclosure of the allegations or transactions alleged in this complaint, Relators are an original source of the information on which this complaint is based. They reported the information to the Government before any public disclosure of the allegations or transactions, have information that is independent of the public disclosure and that information materially adds to any information that the Government may have.

35. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, the Defendants can be found to have transacted business in the Middle District of Tennessee.

36. Venue is proper in the Middle District of Tennessee pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because the Defendants can be found in and/or transact or have transacted business in this district. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this district and maintained employees and offices in this district.

IV. APPLICABLE LAW

A. The False Claims Act

37. The FCA was originally enacted during the Civil War. Congress substantially amended the Act in 1986—and, again, in 2009 and 2010—to enhance the ability of the United

States to recover losses sustained as a result of fraud against it. The Act was amended after Congress found that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments would create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the government's behalf.

38. The FCA prohibits knowingly presenting or causing to be presented to the federal government a false or fraudulent claim for payment or approval and knowingly making or using, or causing to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(A)-(B). Any person who violates the FCA is liable for a civil penalty for each violation, plus three times the amount of the damages sustained by the United States. 31 U.S.C. § 3729(a)(1).

39. For purposes of the FCA, a person "knows" a claim or statement is false if that person: "(i) has actual knowledge of [the falsity of] the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). The FCA does not require proof that a defendant specifically intended to commit fraud. *Id.*

40. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States and to share in any recovery. Such an action is known as a *qui tam* action and the individual bringing the suit is a *qui tam* relator. The FCA requires that the *qui tam* complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

B. Medicare (Part B)

41. Medicare is a federally-funded health insurance program which provides for certain medical expenses for persons who are over 65, who are disabled, or who suffer from End Stage Renal Disease.

42. The Medicare Program has four parts: Part A, Part B, Part C and Part D. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, both inpatient and outpatient, if the services are medically necessary and directly and personally provided by the provider. Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

43. The Medicare program is administered through the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

44. Medicare coverage is limited to those items and services which are reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1). Health care practitioners and providers are required to ensure that all services are "provided economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a)(1),(3). Providers who furnish services or items substantially in excess of the needs of their patients may be excluded from participation in federal health care programs altogether. 42 U.S.C. § 1320a-7(b)(6).

45. Medicare Part B is a voluntary subsidized insurance program covering, inter alia, physicians' services, outpatient hospital care, and laboratory services. Part B's benefits are paid from the federal Supplemental Medical Insurance Trust Fund, which is financed by individual premiums and general federal tax revenues.

46. Medicare Part B pays for "medical and other health care services" provided by a physician, subject to specific exclusions, <u>see</u> 42 C.F.R. § 424.24.

47. Significantly, in order to enroll as a Medicare provider, optometrists, ophthalmologists, practice groups and surgical centers must complete Form CMS-855B. Form CMS-855B requires applicants to certify that they will "abide by the Medicare laws, regulations and program instructions," and to certify their understanding that "payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback statute and the Stark law), and on the supplier's compliance with the applicable conditions of participation in Medicare."

48. By submitting CMS-855B, optometrists, ophthalmologists, practice groups and surgical centers certify that they are eligible for participation in the Medicare Program, and that they have complied with all applicable regulations and laws governing the program, specifically including, but not limited to, the Anti-Kickback Statute.

C. <u>The Medicaid Program</u>

49. Medicaid is a public-assistance program created in 1965 that provides payment of medical expenses for low-income and disabled patients. Funding for Medicaid is shared between the federal government and those states participating in the program. Medicaid is the largest source of funding for medical services for America's poor and disabled. Each provider that participates in the Medicaid program must sign a provider agreement with his or her state.

50. Federal regulations require each state to designate a single state agency responsible for the Medicaid program. The agency must create and implement a "plan for medical assistance" that is consistent with Title XIX of the Social Security Act and with the regulations the Secretary of HHS promulgates. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the items and services for which the federal government will pay through its funding of state Medicaid programs.

51. Like Medicare, Medicaid covers laboratory testing and medical services only if it is necessary to diagnose or treat a patient's particular medical condition. Medicaid routinely pays for testing and services if they meet those standards. Although Medicaid reimbursement for laboratory testing varies depending on the state in which the billing is done, all services provided must meet the medical necessity threshold.

52. Physicians and laboratories receiving reimbursement from Medicaid must make express and/or implied certifications in their state Medicaid provider enrollment forms that they will comply with all federal and state laws applicable to Medicaid.

53. Tennessee has enacted regulations prohibiting kickbacks in connection with State Medicaid services. Pursuant to these regulations, Tennessee has made compliance with federal anti-kickback statutes and rules a prerequisite to receiving or retaining reimbursement payments from state-funded health care programs. See Tenn. Code Ann. § 71-5-118; Tenn. Comp. R. & Regs. 1200-13-18-.07(g).

D. The Anti-Kickback Statute

1. Overview

54. The federal health care Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), ("AKS") arose out of Congressional concern that financial inducements can influence health care decisions and result in goods and services being more expensive, medically unnecessary, and harmful to patients. To protect the integrity of federal health care programs, Congress prohibited the payment of kickbacks in any form, regardless of whether the kickback actually gives rise to overutilization or unnecessary care. The AKS also reaches kickbacks concealed as legitimate transactions. See Social Security Amendments of 1972, Pub. L. No. 92-603, §§242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare and Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

55. The AKS prohibits any person or entity from making or accepting payments to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). The statute prohibits laboratories from offering or paying any remuneration, in cash or kind, directly or indirectly, to induce or influence physicians or others to order or recommend laboratory services that may be paid for by federal health care programs.

56. The AKS has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. An opportunity to earn a fee may be sufficient to constitute an inducement, even if payments were reasonable for services.

57. Compliance with the AKS is a precondition to both participation as a health care provider in and payment under Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, and other federal health care programs.

58. For example, to establish eligibility and seek reimbursement from the Medicare Program, hospitals and other providers enter into Provider Agreements with CMS. As part of that agreement, the provider must sign the following certificate:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

59. Similarly, compliance with the federal AKS is a prerequisite to a provider's right to receive or retain reimbursement payments from government-funded health care programs.

60. In sum, compliance with these terms is at the essence of the bargain and material to the government's decision to pay. In order to receive payment, optometrists, ophthalmologists, and other providers who participate in federal health care programs must

certify explicitly, in a provider agreement or on claim forms, that they have complied with the applicable federal rules and regulations, including specifically the AKS.

61. Any party convicted under the AKS must be excluded from federal health care programs (i.e., not allowed to bill for services rendered) for a term of at least five years. 42 U.S.C. § 1320a-7(a)(1). Even without a conviction, if the Secretary of the Department of Health and Human Services ("HHS") finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agency to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. § 1320a-7(b).

62. The enactment of these various provisions demonstrates Congress' commitment to the fundamental principle that federal health care programs will not tolerate the payment of kickbacks. Thus, compliance with the AKS is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicare and other federal health care programs.

63. Furthermore, pursuant to the Affordable Care Act passed in 2010, any claim submitted to a federal health care program that includes items or services resulting from violations of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act. 42 U.S.C. § 1320a-7b(g).

2. No Safe Harbor for Global Fee Splitting Arrangements

64. HHS has promulgated certain safe harbor regulations that define practices that are not subject to the AKS, including referral arrangements for specialty services. 42 C.F.R. § 1001.952(s).

65. When developing the AKS Safe Harbors, HHS-OIG declined to extend the specialist referral arrangement safe harbor to situations with a split global fee or bundled payment. In declining to extend the safe harbor, OIG specifically cited concerns with potentially abusive ophthalmologist-optometrist agreements for Medicare funded cataract surgeries. HHS-

OIG noted numerous commentary on potentially abusive co-management relationships, concluding that "the serious issues raised by the ophthalmologists about ***apparently routine or blanket agreements to split global Medicare fees with referring optometrists*** (as well as other information that has come to our attention from industry and Government sources) has caused us to modify the scope of this safe harbor." 64 Fed. Reg. 63,518, 63,548-63, 548 (Nov. 19, 1999) (emphasis added). Potential AKS violations in global fee splitting agreements are evaluated by OIG on a "case-by-case analysis of all of the facts and circumstances…" Id. at 63,549.

66. While there are many factors to determine whether co-management is a violation, a primary threshold question is whether agreements are blanket or routine.

67. In an advisory opinion in 2011, HHS-OIG reaffirmed concerns about blanket or routine co-management agreements. HHS-OIG evaluated an issue related to co-managed Medicare patients receiving Premium IOLs. See HHS-OIG Advisory Opinion No. 11-14, issued Sept. 30, 2011. In such a case, a referring optometrist co-managing the patient would receive funds from Medicare for post-operative care, and additional funds from the patient for the refractive vision correction services. HHS-OIG evaluated the narrow question of whether these additional patient-funded fees for vision correction constituted impermissible "remuneration" under the Anti-Kickback Statute. Id. at 5.

68. The Advisory Opinion specifically stated that OIG was not asked to opine on the issue of whether the opportunity to earn a fee on co-management of a "conventional IOL" surgery, which is paid by Medicare, violates the AKS. Id. at n.4.

69. In finding that the limited practice set forth by the Requestor did not violate the AKS, OIG relied on several policies the Requestor certified it followed, including that ***co-management was not routine or automatic***, and that transfers back to optometrists only occurred upon a patient's informed request. Id. at 6 (emphasis added).

70. The Opinion furthermore reiterated OIG's previous concerns about routine co-management in ophthalmologist/optometrist networks, citing a problematic example where

optometrists only referred patients to ophthalmologists who agreed to co-manage and split the global fee, often without regard to clinical appropriateness. Id. at n.4.

V. BACKGROUND

A. Cataract Surgery

71. A cataract is a clouding of the human ocular lens, impairing vision. In cataract surgery, the natural lens is removed and replaced with an artificial lens, also known as an intraocular lens (IOL). By age 80, 50% of Americans have experienced cataracts or have had cataract surgery.

72. Traditional cataract surgery includes the insertion of a "conventional IOL." This procedure removes the cloudy lens, however, the new artificial lens will not correct any pre-existing vision issues. Individuals requiring vision correction still require glasses or contact lenses. Medicare covers cataract surgery as a global surgical procedure, which means that Medicare pays one global fee for the pre-operative care, the surgery, and the post-operative care for 90 days following the surgery.

73. A patient may also elect to receive a "premium IOL" that also corrects refractive vision problems, and reduces an individual's dependence on glasses or contact lenses after surgery. Medicare does not pay for additional fees associated with a "premium IOL": these must be covered out of pocket by the patient or private insurance. A Medicare patient receiving a "premium IOL" therefore has surgery and care paid for by Medicare, and additional vision correction fees paid for out of pocket.

74. Medicare and Medicaid allow billing for ***appropriate*** co-management of a patient between an optometrist and ophthalmologist. CMS sets the global surgical fee split, allowing the ophthalmologist providing surgery to collect 80% of the global fee, and the optometrist providing post-operative care 20%. Providers bill for their portion of care using CMS modifier codes -54 (surgical care only) and -55 (post-operative management only).

75. Medicare or Medicaid-reimbursed co-management agreements must comply with the Anti-Kickback Statute.

B. <u>Appropriate Co-Management Arrangements</u>

76. The American Academy of Ophthalmology is the largest professional association of ophthalmologists. The AAO has released a number of position papers/guidance documents on ophthalmologist-optometrist co-management agreements, cautioning against routine co-management.

77. A 2000 joint position paper, issued with the American Society of Cataract and Refractive Surgery, emphasized that co-management was to be "an ***exceptional***, rather than a routine, occurrence." American Academy of Ophthalmology et. al., <u>Joint Position Paper: Ophthalmic Postoperative Care.</u> (2000), <u>available at</u> http://www.ascrs.org/sites/default/files/resources/Joint%20ASCRSAAO%20Co-Management%20Guidelines.pdf. It also stated that "co-management must not be done as a matter of routine policy" and if it "is done on a routine basis for predominately financial reasons, it represents unethical behavior and may be illegal."

78. While the American Optometric Association did not adopt the "exceptional, rather than routine" language, it nevertheless emphasized in its paper issued in 2000 that co-management of post-operative care should be "determined on a case-by-case basis and not prearranged." American Optometric Association, <u>Optometric Postoperative Care,</u> (Apr. 27, 2000), <u>available at</u> https://www.aoa.org/Documents/about/06b_Other_AOA_Postoperative_Care_Position Paper.

79. In 2015, the AAO noted that a criteria of appropriate co-management that "must be met" included that there was "no agreement between the operating ophthalmologist and a referring non-operating practitioner to automatically send patients back to the non-operating practitioner." American Academy of Ophthalmology et. al., <u>Ophthalmic Postoperative Care: A Joint Position Paper of the American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery</u> (June 2015), available at http://www.ascrs.org/sites/default/files/

resources/ComanagementJointPositionPaperSept2015c.pdf.

80. In 2016, the AAO again emphasized that "***routine co-management or transfer of care referral arrangements are not appropriate.*** Instead, co-management and transfer of care arrangements should be conducted pursuant to written patient-specific protocols where each of the following criteria are met, [such as having] no agreement or understanding between the operating ophthalmologist and a referring non-operating practitioner to automatically send patients back to the non-operating practitioner." American Academy of Ophthalmology et. al., Comprehensive Guidelines for the Co-Management of Ophthalmic Postoperative Care. (Sept. 7, 2016) (emphasis added), available at https://www.aao.org/ethics-detail/guidelines-comanagement-postoperative-care.

81. In sum, the prohibition against routine cataract co-management agreement was widespread and extensively disseminated by professional societies, professional journals, articles, professional guidelines and regulations, and in an OIG opinion such that anyone engaged in these agreements, including Defendants, would have actual knowledge of this prohibition and its illegality.

82. Appropriate clinical circumstances for co-management include, for example, situations where the patient must travel a further distance to receive post-operative care from the ophthalmologic surgeon than their referring optometrist. Other patient circumstances may affect whether co-management is clinically appropriate. For example, patients should typically stay with their surgeon for post-operative care if any complications arise from surgery.

83. One recent study evaluated rates of cataract patient co-management for Part B Medicare participants. The average rate of co-management of cataract surgery by ophthalmologists and optometrists among Medicare beneficiaries was 10.9% in 2012 and 11.1% in 2013. In Tennessee, co-management rates were 22.3% in 2012 and 22.1% in 2013. Jay C. Erie et. al., Joint Management of Cataract Surgery by Ophthalmologists and Optometrists, 123 Ophthalmology 3, 505, 505-6 (2016).

84. By contrast, SEES representatives have noted in seminars—to an audience of potentially referring optometrists—that their co-management rates exceed 70% and may, in fact, be up to 95%.

VI. ALLEGATIONS

A. SEES uses routine co-management agreements as inducement to increase optometrist referrals.

85. SEES has created a business model driven by routinely entering patient co-management agreements with referring optometrists. In doing so, SEES implicitly guarantees to referring optometrists that they will receive fees associated with patient post-operative care.

86. SEES promotes this practice to optometrists by frequently sponsoring, and inappropriately providing, free continuing medical education courses and dinners for optometrists in Nashville and other locations across Tennessee. Continuing medical education courses are a requirement of continued professional certification for optometrists, and seminars typically cost $25-$50 per credit. SEES offers 2-credit or more seminars, dinners, and open bars per event—free to participants—equaling more than $100 in value for each event.

87. SEES' continuing medical education courses target potential referring optometrists. The subject matter covered by the courses provide optometrists training on post-operative cataract and glaucoma surgery care. The seminars also offer optometrists training on Medicare coding related to co-management. Biographies for speakers at a number of seminars emphasize experience with co-management models.

88. SEES advertises these seminars to optometrists through email, social media, and direct mail campaigns. SEES representatives also visit the offices of potential referring optometrists personally, to invite the optometrists to sponsored events.

89. Relator Dr. Lumpkin attended SEES sponsored seminars on three separate occasions: a seminar on "Enhancing Cataract Surgery Outcomes" (June 20, 2016 in Nashville, TN), a second seminar on "Co-Management of SLT Application and the Optometrist's Role in Pre-Op IOL Calculations" (Sept. 9, 2016 in Hendersonville, TN), and a third seminar on "Ocular

Cicatricial Pemphigoid" (Dec. 6, 20216 in Nashville, TN). Dr. Lumpkin documented each of these seminars with audio recordings.

90. In these seminars, SEES representatives repeatedly touted their routine co-management as a revenue opportunity for referring optometrists. SEES attempted to routinize co-management by holding seminars to encourage optometrists to direct patients into expecting co-management prior to surgery. SEES furthermore encouraged optometrists to skip post-operative visits for certain co-managed procedures, despite being paid by Medicare to see the patients.

1. *Co-Management as Pre-Existing Agreement; Pressuring Patients*

91. At the June 20th seminar, SEES Co-Founder and Chief Manager Dr. Daryl Mann emphasized to his audience of optometrists that "for the most part, ***our real goal is to keep as much patient revenue in your practice as we can***." Dr. Mann continued to note that SEES is "very good at trying to build *your* relationship with your patient…our patients, ***our clients are you all.***" Dr. Mann further offered training to any optometrists who were not doing post-operative care on patients and would like to, noting that "again, we want this patient to get as much services in your office as possible."

92. Dr. John Bierly, SEES Co-Founder and ophthalmic surgeon, similarly noted in this seminar that SEES was "***as a company […], committed to working with optometrists in a co-management system."*** Dr. Bierly noted that "the ophthalmologists we hire are committed to doing that," and suggested that referring optometrists would be pleased with how SEES could ***"help you grow your practices."***

93. In this same seminar, Dr. Daryl Mann also emphasized that referred patients ***"should come in already expecting (co-management)."*** Because co-management requires patient consent, Dr. Mann noted it was critical for optometrists to ***"let your patient know that they're coming back to see you for post-operative care."*** Absent this steering from the

optometrist, Dr. Mann noted that patients may question why they would return to the optometrist instead of staying with the surgeons for post-operative care.

94. Similarly, in the December 6th seminar, SEES ophthalmic surgeon Dr. William Goodman repeated that patients are "the ultimate decider," but should arrive from a referring optometrist "with the notion that ***co-management has already been set in place***." Dr. Goodman noted that because patients expected co-management coming into surgery, only a single SEES patient opts-out of co-management every five months or so.

95. Despite national co-management averages of ~10% and averages of ~20% in Tennessee (including SEES—the largest referral practice in Tennessee), SEES promotes in seminars that they co-manage upwards of 70-75% of patients, or even as high as 90-95%.

96. SEES also signals its commitment to co-managing with optometrists through social media and newsletters. On the surgical center's online homepage, a number of biographies for SEES' M.D.s and O.D.s emphasize their interest in and commitment to co-managing surgical patients. SEES describes itself as a "referral based co-management eye center" on newsletters and social media. SEES has also published newsletter articles on various surgical options in cataract surgery targeted to co-managing optometrists, describing precisely the fee a co-managing optometrist would be entitled to under different surgical options.

2. ***<u>Guaranteeing Revenue and Business Opportunities for Referrals</u>***

97. Beyond allowing optometrists to collect 20% of the Medicare/Medicaid global surgical fee, SEES' routine co-management also allows optometrists to collect an additional approximately 10% in fees where the patient elects to have vision-correcting cataract surgery (as opposed to traditional cataract surgery). The Tennessee Fee payment schedule for cataract surgery is approximately $600. SEES offers two vision correcting "premium IOL" options: one adds $1,695 of patient funded fees per eye (with $150 per eye as the optometrists' co-management fee), and another which adds $2,995 of patient funded fees per eye (with $300 per eye as the optometrists' co-management fee).

98. For referring a Medicare patient whom elects a "premium IOL" to SEES, the co-managing optometrist would therefore receive $120 from Medicare, and either $150 or $300 from the patient, for a total of up to $420 per eye.

99. By contrast, no revenue would be guaranteed when referring to a practice that did not routinely co-manage patients.

100. SEES advertises in seminars that it will collect out-of-pocket fees for vision correcting "premium IOLs," and ***deliver monthly checks*** to referring optometrists for their share.

101. Routine co-management not only guarantees referring optometrists fees for post-operative care: it ensures the patient will return to the referring optometrist for other services. In addition to post-operative care, surgical patients typically return for a number of follow up examinations 6-12 months after surgery, and for yearly exams. At this time, the majority of cataract patients will also require glasses or other optical services. Medicare covers the costs of one pair of eyeglasses after cataract surgery.

102. SEES and referring optometrists understand that many referrals are not primarily based on the patient's best interests: instead, they are based on economic motivations. SEES actively restricts members of its surgical group from offering services that may compete with the business of referring optometrists. Relators were told by a colleague that one SEES surgeon, who had ceased providing routine eye care or optical services after joining SEES, wrote a prescription for glasses including the note "personal friend of doctor." On information and belief, the SEES surgeon included the note in fear that optometrists would cease providing patient referrals to SEES if they believed the group was offering competing businesses. Similarly, Relator Mr. Gary Odom discussed patient referral practices with a Nashville optometrist running a large practice: asked why he worked almost exclusively with SEES, the optometrist replied, "Gary, it's all about money."

103. By funneling the patient back to the optometrist after a surgery, SEES helps to guarantee that in exchange for a referral, optometrists will maintain these lines of revenue themselves.

104. SEES similarly actively advertises efforts to aggressively “convert” M.D. referrals “back to optometric community [to] backfill [optometrists’] practice.” At the December 6th seminar, the SEES Center Director noted that if SEES can’t “convert” an M.D. patient by phone, they will accept the patient from the primary care doctor, then let patient know “up front” no primary routine care is provided by SEES, then “turn around then try to get them in [an optometrists’] office.”

105. In sum, optometrists are repeatedly promised increased revenue—through Medicare funded post-operative fees, patient funded vision correction fees, and increased business referrals and a promise not to compete—in exchange for referring patients to SEES over other practices.

3. ***Compromising Patient Care***

106. Significantly, the use of routine co-management agreements to induce patient referrals is not only a violation of the Anti-Kickback Statute: it creates risks for patient care. Routine co-management creates systemic incentives for overutilization of cataract surgery, including pushing for surgery at earlier stages of a cataract, surgery occurring at earlier patient ages, and a higher incident of potentially unnecessary surgeries. SEES’ use of routine co-management lowers incentives for optometrists to refer patients to the most appropriate surgeons.

107. SEES fraudulently co-manages patients with optometrists when a post-operative visit is not clinically necessary. In a September 27th seminar attended by Dr. Lumpkin, SEES Center Director Dr. Robin Brady described how optometrists should manage patients after Medicare funded glaucoma surgery, which has a 10-day post-operative period. Dr. Brady noted that Medicare reimbursement for the post-operative care is only $51: by contrast, for cash pay

patients, SEES receives $500 for each procedure and "$100 of it goes to you." Dr. Brady then noted that "you guys … have to decide—is this visit necessary or not? Medicare is paying you for it, so you might want to do it." Dr. Brady then implicitly endorsed skipping Medicare funded post-operative care, noting that one SEES surgeon "just doesn't do it."

108. Given that one of the principal reasons for co-management is geographic distance of the patient from the surgeon, which is typically found in rural areas, it is hard to imagine that SEES could clinically justify co-management for all of the 70-95% of patients that they co-manage in urban centers of Chattanooga, Knoxville and Nashville. Referring optometrists for patients in these cities are therefore not likely to be significantly closer to the patient than the SEES surgical center.

109. SEES' use of routine co-management may also compromise patient care and assessments of clinical appropriateness. On the June 20th seminar, SEES Chief Manager Dr. Daryl Mann emphasized to his audience of optometrists that SEES will never "throw [optometrists] under the bus," even if a diagnosis is missed. Specifically citing an example of cataract patients with glaucoma—patients which can be at higher risk for post-operative complications—Dr. Mann emphasizes that SEES optometrists "will not say much about [the glaucoma] . . . it's your patient . . . we're not going to take over that care if you don't want us to. ***We'll agree with your diagnosis***."

110. SEES' commitment to guaranteeing that referring optometrists keep other patient business also interferes with patient care. On information and belief, SEES bars its surgeons from any patient contact that is not directly related to the patients' surgery: the surgeons do not meet or examine patients prior to the surgical procedure. The purpose of this practice is to ensure referring optometrists that they offer no competition for other optical services, though it is not necessarily in the best interests of the patient nor in line with professional norms.

111. SEES claims to perform ~12,000 cataract surgeries a year between the Knoxville, Chattanooga, and Nashville facilities. The majority of these are likely Medicare patients given the age at which cataracts affect most patients. The Tennessee Fee payment schedule for each of

these cataract surgeries is approximately $600. Additional initial exam fees for each patient are approximately $100, and other ancillary testing fees may be billed depending on the patient.

112. In Knoxville and Chattanooga, SEES has exclusively performed these procedures at Southeast Eye Surgery Center, LLC and Eye Surgery Center of Chattanooga, LLC's facilities. For each Medicare funded surgery, these centers received additional facility and other fees (including for example anesthesia), typically exceeding the professional/physician fees. As a result of the kickback scheme, Southeast Eye Surgery Center, LLC and Eye Surgery Center of Chattanooga, LLC received approximately $900 in Medicare funds per surgery. The sole officers of these two ambulatory surgical treatment centers are SEES officers who were involved in and had knowledge of the fraudulent co-management scheme.

113. In sum, these illicit co-managed surgeries have resulted in tens of millions of dollars billed to Medicare and Medicaid.

114. SEES also practices routine co-management to induce patient referral for other Medicare funded procedures, including YAG capsulotomy for cataract related vision improvement, and Selective Laser Trabeculoplasty for glaucoma treatment. In the December 6th seminar, Dr. Robin Brady emphasized to his audience of optometrists that "every surgery that we provide is co-manageable, to a point that CMS allows a co-management code."

115. On information and belief, ophthalmologic practices across the country impermissibly use routine co-management agreements to induce patient referrals. Relators possess continuing medical education seminar fliers from ophthalmologic practices across the country emphasizing co-management for cataract surgery and other procedures. SEES founders have noted that their co-management model was based that of "OMNI Eye Services"—a series of surgical groups described as a "co-management centers" with practices nationwide, including Atlanta, GA and New York, NY. SEES Co-Founder and Center Director Dr. Daryl Mann had previously served as a Center Director for an OMNI surgical center, and Dr. Mann has told Relator Gary Odom that current and former OMNI Center Directors still regularly convene.

B. <u>Defendants defrauded at least one Medicare HMO which prohibits global fee splitting.</u>

116. At least one Medicare HMO in Tennessee (HealthSpring) refuses to recognize co-management global fee splitting. Despite this restriction, SEES induces HealthSpring patient referrals by offering optometrists a form of co-management.

117. SEES represents to HealthSpring that SEES surgeons will not split the Medicare global fee, and will treat patients for post-operative care. However, SEES actually encourages referring optometrists to offer HealthSpring Medicare patients "free" post-operative care. If a Medicare patient upgrades to a "premium IOL" with vision correcting services, and the optometrist has offered to see the patient "for free" for post-operative care, SEES pays the optometrist approximately 10% of the patient funded "premium IOL" fee. In the December 6th seminar, SEES Center Director Dr. Robin Brady described and encouraged this practice.

118. In other words, in exchange for Medicare patient referrals, SEES guarantees it will directly pay optometrists a fraction of the patient funded vision correction fee, or approximately $300 per procedure.

119. In addition, SEES effectively compensates optometrists for post-operative care through this system, despite representing to Medicare it does so itself.

C. <u>Defendants and referring optometrists violated the Anti-Kickback Statute.</u>

120. Through routine co-management, Defendants improperly incentivize optometrists to increase patient referrals to their practice. Normally, a referring optometrist should have no expectation about a cataract patient returning to his/her practice for post-surgical care, and no expectation regarding a global fee split. When referring a patient to SEES, by contrast, optometrists are implicitly guaranteed: 20% of the patient's Medicare or Medicaid global surgery fee, ~10% of the patient-funded vision correction fees (if applicable), and return of the patient's future business to the optometrist.

121. Defendants' practices defy standards set by the largest professional association of ophthalmologists, and repeated concerns about this exact arrangement from HHS-OIG. Both professional standards and HHS-OIG's opinions emphasize the importance of patient choice, assessments of clinical appropriateness, and refraining from automatic/blanket agreements.

122. Instead, Defendants have created a practice where routine co-management is an unwritten, pre-existing agreement with referring optometrists. Defendants collude with referring optometrists to undermine patient choice, emphasizing that patients are to "expect" co-management from the onset of diagnosis from the referring optometrist.

123. One purpose of this practice is clearly to increase referrals, as is evident from SEES' business model, and statements made by SEES' Directors and upper level management in sponsored seminars.

124. Defendants were involved in the creation and marketing of the scheme and have knowledge that routine co-management agreements violate the AKS.

125. Each claim submitted in violation of the AKS is a false claim within the meaning of the False Claims Act. Thus, through their illegal conduct, Defendants have submitted thousands of false or fraudulent claims to Medicare, Medicare Advantage providers and other government health care programs.

Count I
False Claims Act
31 U.S.C. §§ 3729(a)(1)(A)(B) & (G)

126. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 125 above as though fully set forth herein.

127. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.

128. By and through the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

129. By and through the acts described above, Defendants knowingly made, used or caused to be made or used, false statements or records material to false or fraudulent claims.

130. By and through the acts described above, within the meaning of the False Claims Act, Defendants knowingly concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

131. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

132. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

133. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every violation alleged herein occurring prior to November 2, 2015, and $21,563 for each violation occurring after.

Count II
Tennessee False Claims Act and Tennessee Medicaid False Claims Act
Tenn. Code Ann. §§ 4-18-103(a)(1)– (2), (7) and §§ 71-5-182(a)(1)(A)–(B), (D)

134. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 133 above as though fully set forth herein.

135. This is a claim for treble damages and penalties under Tennessee False Claims Act and Tennessee Medicaid False Claims Act.

136. Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

137. By and through the acts described above, Defendants knowingly concealed and improperly avoided or decreased an obligation to pay money to the Tennessee State Government.

138. Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

139. The Tennessee State Government, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

140. Defendants have damaged, and continue to damage, the State of Tennessee in a substantial amount to be determined at trial.

141. Additionally, the Tennessee State Government is entitled to the maximum penalties pursuant to the Tennessee False Claims Act and the Tennessee Medicaid False Claims Act for each and every violation alleged herein.

VII. PRAYER

WHEREFORE, *qui tam* Relators pray for judgment against the Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729 et seq.;

2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729 occurring prior to November 2, 2015, and not less than $10,781 and not more than $21,563 for each violation of 31 U.S.C. § 3729 occurring after November 2, 2015.

3. That Relators be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and the Tennessee False Claims Act and Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 4-18-103(a)(1)–(2) and §§ 71-5-182(a)(1)(A)–(B);

4. That Relators be awarded all costs of this action, including attorneys' fees and expenses; and

5. That Relators recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, *qui tam* Relators Gary Odom and Ross Lumpkin hereby demand a trial by jury.

Dated: April 7, 2017

Respectfully submitted,

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